SEHSC SILICONES ENVIRONMENTAL, HEALTH AND SAFETY COUNCIL of North America

April 4, 2003
VIA ELECTRONIC AND U.S. MAIL

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852

RE: SEHSC Comments on the FDA Proposed Regulation, Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. [Docket No. 02N-0276]

Dear Madam or Sir:

The Silicones Environmental, Health and Safety Council of North America (SEHSC) hereby respectfully submits these comments with regard to the Proposed Regulation on Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 published in the Federal Register on February 3, 2003 (68 *Fed. Reg.* 5377).

SEHSC is a not-for-profit trade association whose mission is to promote the safe use and stewardship of silicones. The Council is comprised of North American silicone chemical producers and importers. SEHSC's members represent over 95 percent of silicone chemical manufacturing capacity in North America and include: Clariant LSM (Florida), Inc.; Crompton Corporation; Degussa Corporation; Dow Corning Corporation; General Electric Silicones; Rhodia Inc.; Shin-Etsu Silicones of America; and Wacker Silicones. SEHSC member companies provide silicone-based resins that are used to make, among other things, coatings, films, and adjuvants that are used in packaging materials, including packaging for food products.

SEHSC asserts that the prior notice requirement with respect to materials defined as food contact materials or indirect food additives is contrary to congressional intent. FDA has proposed to include suppliers of materials which do not contain food within the reach of the regulations by using the definition of "food" found in Section 201 (f) of the Federal Food, Drug, and Cosmetic Act (FFDCA) which defines "food" as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article," which includes food additives. Section 201(s) of the FFDCA defines a food additive to include "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly in its becoming a component or otherwise affecting the characteristics of any food." This definition covers all the food additive substances listed in 21 CFR §§170-199, including those used in food packaging and other articles that contact food.

Such a broad definition in the proposed regulation with respect to food contact materials is contrary to the intent of Congress, which was intended to cover only "food for consumption in the United States."

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The regulation should be clarified to define "food for consumption" as referring to edible food and not food contact materials, indirect food additives, or substances that might migrate to food.

This broad definition of "food" requires that facilities that manufacture or import materials that may be used for the manufacture of food contact articles such as conveyor belts, oven gaskets, coatings on metal substrates, adhesives, antifoam agents used in food processing, components of polyolefin films, colorants used in polymers, rubber articles, release coatings, etc, to register their facilities with FDA. This will impose a significant burden on the silicone industry companies because most of the materials used in food contact applications are primarily used as industrial non-food contact materials. In most cases, it is impossible to know if a silicone material will be used, for example, to mold parts for an automobile gasket or for an oven gasket. Thus, this regulation will effectively require registration of all facilities that manufacture or handle silicones in the U.S. because the owners/operators will not know whether some of their product may end-up in a food contact application.

Additionally, including food contact materials and their components in the regulation will impose burdens on the industry that are disproportionate to any minimal risk from and will provide no protection against terrorism. The requirement would apply not just to facilities that manufacture food contact materials but also to the warehouses where they are stored. An inordinate amount of time will have to be spent simply identifying the facilities that have to be registered and in putting into place the procedures to meet this obligation including the proposed updates. It is our belief that this information will have limited usefulness in FDA's abilities to prevent and respond effectively to terrorist threats against our food supply. Registration of facilities that manufacture or store food contact materials or indirect food additives would not deter the intentional contamination of food or assist the FDA in determining the source and cause of contamination. Food contact materials, indirect food additives, or substances that might migrate to food have not been connected to any occurrences of food borne illness from accidental or intentional contamination of edible food.

In conclusion, the requirement on industry to register facilities that manufacture and store "food" should not be extended to any food contact materials, indirect food additives, or substances that might migrate to food and which do not already contain food or are in contact with edible food. FDA's proposed regulation is contrary to congressional intent and will not provide any significant assistance to FDA in deterring or responding to terrorism directed at the food supply.

SEHSC appreciates the opportunity to provide comments on this proposed regulation. Please contact me at (703) 904-4322 if you need further clarification, or if SEHSC can be of assistance.

Sincerely,

Reo Menning
Executive Director